

Notice of Allowability

Application No.

09/818,086

Examiner

Joyce Tung

Applicant(s)

BASKIN ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/12/07.
2. ☒ The allowed claim(s) is/are claims 26-50 (final claims 1-25).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>4/27/07</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

The applicant's response filed 4/12/07 to the Office action has been entered. Claims 26-50 are pending.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Jennifer Davis on 4/27/07.

2. The application has been amended as follows:

In claim 48, line 2, delete "SYBR Green I" and substitute – unsymmetric cyanine dye --.

3. The following is an examiner's statement of reasons for allowance:

Concerning claims 26-50, no prior art has been found teaching or suggesting a method of determining the presence and sequence of at least one target polynucleotide in a sample, The method comprising combining a nucleic acid sample with at least one set of reaction compositions comprising a first reaction composition and a second reaction composition wherein the first reaction composition comprises amplification primers specific to the at least one target polynucleotide and lacks a fluorescent indicator and the second reaction composition comprises a fluorescent indicator and amplification primers specific to the at least one target polynucleotide and wherein the first reaction composition and the second reaction composition are separate, amplifying the target polynucleotide using the amplification primers, irradiating the amplification product of the second reaction composition wherein the intensity of the fluorescent

Art Unit: 1637

signal is related to the quantity of the at least one amplification product, monitoring the amplifying of the second reaction composition by detecting the fluorescent signal, determining whether the at least one amplification product is present in both reaction compositions from the intensity of the fluorescent indicator in the second reaction composition and determining the sequence of the at least one amplification product of the first reaction composition if the at least one amplification product is present in the first reaction composition.

The closest prior art is the reference of Wittwer et al. (6,174,670). Wittwer et al. disclose the method of monitoring hybridization during polymerase chain reaction using a double stranded DNA dye or specific hybridization probes and quantitating amplified DNA (See the Abstract). Wittwer et al. do not disclose that one of the reaction compositions lacks a fluorescent indicator, determining whether the at least one amplification product is present in both reaction compositions from the intensity of the fluorescent indicator in the second reaction composition and determining the sequence of the at least one amplification product of the first reaction composition if the at least one amplification product is present in the first reaction composition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung *JT*
April 29, 2007

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/3/07